

KATTEN MUCHIN ROSENMAN LLP
KRISTIN L. HOLLAND (SBN 187314)
kristin.holland@kattenlaw.com
TAMI KAMEDA SIMS (SBN 245628)
tami.sims@kattenlaw.com
2029 Century Park East, Suite 2600
Los Angeles, CA 90067-3012
Telephone: 310.788.4400
Facsimile: 310.788.4471

KATTEN MUCHIN ROSENMAN LLP
James J. Calder (*admitted pro hac vice*)
james.calder@kattenlaw.com
Mark T. Ciani (*admitted pro hac vice*)
mark.ciani@kattenlaw.com
575 Madison Avenue
New York, NY 10022-2585
Telephone: 212.940.8800
Facsimile: 212.940.8776

Attorneys for Plaintiff Retrophin, Inc.

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION**

**RETROPHIN, INC., a Delaware
Corporation,**

Plaintiff,

VS.

**QUESTCOR PHARMACEUTICALS,
INC., a California Corporation,**

Defendant.

CASE NO. 14-CV-00026-JLS (JPRx)
[Hon. Josephine L. Staton]

**PLAINTIFF RETROPHIN INC.'S
MEMORANDUM OF POINTS AND
AUTHORITIES IN OPPOSITION TO
DEFENDANT QUESTCOR
PHARMACEUTICAL INC.'S
MOTION TO DISMISS**

**Hearing Date: May 30, 2013
Time: 2:30 p.m.**

[Proposed] Order filed concurrently herewith]

TABLE OF CONTENTS

		Page
1	I. PRELIMINARY STATEMENT	1
2	II. STATEMENT OF FACTS.....	3
3	A. Allegations in the Complaint	3
4	B. Factual Assertions in Questcor's Motion.....	5
5	III. ARGUMENT.....	7
6	A. STANDARDS FOR MOTION TO DISMISS.....	7
7	B. Retrophin Alleges Antitrust Injury and Antitrust Standing	7
8	1. Retrophin Alleges Antitrust Injury and Threat of Injury.....	7
9	2. Retrophin Alleges Antitrust Standing.....	11
10	C. RETROPHIN ALLEGES MARKET AND MONOPOLY POWER AND HARM TO COMPETITION.....	16
11	1. Retrophin Alleges Market and Monopoly Power.....	16
12	1. Retrophin Alleges Harm to Competition.....	19
13	D. RETROPHIN ALLEGES AN ATTEMPT TO MONOPOLIZE CLAIM	22
14	E. RETROPHIN ALLEGES AN ABSENCE OF BUSINESS JUSTIFICATIONS	23
15	F. RETROPHIN PROPERLY ALLEGES STATE LAW CLAIMS	24
16	IV. CONCLUSION	25
17		
18		
19		
20		
21		
22		
23		
24		
25		
26		
27		
28		

TABLE OF AUTHORITIES

		Page(s)
1	Cases	
2	<i>Adaptive Power Solutions, LLC v. Hughes Missile Sys. Co.</i> , 141 F.3d 947 (9th Cir. 1998)	23
4	<i>Alberta Gas Chemicals Ltd. v. E.I. Du Pont De nemours & Co.</i> , 826 F.2d 1235 (3d Cir. 1987).....	9
6	<i>Allied Orthopedic Appliances Inc. v. Tyco Health Care Group LP</i> , 592 F.3d 991 (9th Cir. 2010)	21
8	<i>Am. Tobacco Co. v. United States</i> , 328 U.S. 781 (1946).....	18
10	<i>AMA v. United Healthcare Corp.</i> , No. 00 Civ. 2800 (LMM), 2007 WL 683974 (S.D.N.Y Mar. 5, 2007).....	14
12	<i>American Professional Testing Service, Inc. v. Harcourt Brace Jovanovich Legal & Professional Publications, Inc.</i> , 108 F.3d 1147 (9th Cir. 1997)	23
14	<i>Andrx Pharm., Inc. v. Biovail Corp. Int'l</i> , 256 F.3d 799 (D.C. Cir. 2001).....	9, 13, 15, 24
16	<i>Antoine L. Garabet, M.D., Inc. v. Autonomous Technologies Corp.</i> , 116 F. Supp. 2d 1159 (C.D. Cal. 2000).....	14
18	<i>Apex Oil Co. v. DiMauro</i> , 713 F. Supp. 587 (S.D.N.Y. 1989)	23
20	<i>Ashcroft v. Iqbal</i> , 556 U.S. 662 (2009).....	7
22	<i>Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters</i> , 459 U.S. 519 (1983).....	12
24	<i>Axis, S.p.A. v. Micafil, Inc.</i> , 870 F.2d 1105 (6th Cir. 1989)	11
26	<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544 (2007).....	7

Katten
Katten Muchin Rosenman LLP

2029 Century Park East, Suite 2600
Los Angeles, CA 90067-3012
310-383-4400 tel 310-738-4471 fax

TABLE OF AUTHORITIES

	Page(s)
1 <i>Bigelow v. RKO Radio Pictures</i> , 2 327 U.S. 251 (1946).....	12, 16, 23
3 <i>Borough of Lansdale v. Philadelphia Elec. Co.</i> , 4 692 F.2d 307 (3d Cir. 1982)	23
5 <i>Bristol-Myers Squibb Co. v. Copley Pharm., Inc.</i> , 6 144 F. Supp. 2d 21 (D. Mass. 2000).....	15
7 <i>Broadcom Corp. v. Qualcomm Inc.</i> , 8 501 F.3d 297 (3d Cir. 2007)	14, 18, 25
9 <i>Brotech Corp. v. White Eagle Int'l Technologies Grp., Inc.</i> , 10 CIV.A.03-232, 2004 WL 1427136 (E.D. Pa. June 21, 2004)	15
11 <i>Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.</i> , 12 429 U.S. 477 (1977).....	8
13 <i>Bubar v. Ampco Foods, Inc.</i> , 14 752 F.2d 445 (9th Cir. 1985)	13
15 <i>California ex rel. Van de Kamp v. Texaco, Inc.</i> , 16 46 Cal. 3d at 1168).....	26
17 <i>Carefusion Corp. v. Medtronic, Inc.</i> , 18 10-CV-01111-LHK, 2010 WL 4509821, at *9 (N.D. Cal. Nov. 1, 19 2010)	14
20 <i>Cargill, Inc. v. Monfort of Colo. Inc.</i> , 21 479 U.S. 104 (1986).....	8
22 <i>Chelson v. Oregonian Pub. Co.</i> , 23 715 F.2d 1368 (9th Cir. 1983)	13
24 <i>City of Pittsburgh v. W. Penn Power Co.</i> , 25 147 F.3d 256 (3d Cir. 1998)	11, 21
26 <i>F.D.I.C. v. Faigin</i> , 27 No. CV 12-03448, 2013 WL 3389490 (C.D. Cal. July 8, 2013).....	24
28 <i>FTC v. Atl. Richfield Co.</i> , 29 549 F.2d 289 (4th Cir. 1977)	22

TABLE OF AUTHORITIES

		Page(s)
1	<i>Glen Holly Entertainment, Inc. v. Tektronix, Inc.</i> , 352 F.3d 367 (9th Cir. 2003)	<i>passim</i>
3	<i>Gulf States Reorganization Grp., Inc. v. Nucor Corp.</i> , 466 F.3d 961 (11th Cir. 2006)	8
5	<i>Image Technical Servs. v. Eastman Kodak Co.</i> , 125 F.3d 1195 (9th Cir. 1997)	17
7	<i>In re ATM Fee Antitrust Litig.</i> , No. C 04-2676, 2010 WL 2557519 (N.D. Cal. Jun. 21, 2010)	18
9	<i>In re Champion Spark Plug Co.</i> , 103 F.T.C. 546, 1984 WL 565371 (1984).....	22
10	<i>In re Dual-Deck Video Cassette Recorder Antitrust Litig.</i> , 11 F.3d 1460 (9th Cir. 1993)	8, 13
12	<i>In re Relafen Antitrust Litig.</i> , 286 F. Supp. 2d 56 (D. Mass. 2003).....	21
14	<i>Lee v. City of Los Angeles</i> , 250 F.3d 668 (9th Cir. 2001)	5, 25
16	<i>Lucas Auto. Eng'g, Inc. v. Bridgestone/Firestone, Inc.</i> , 140 F.3d 1228 (9th Cir 1998)	9
18	<i>Masimo Corp. v. Tyco Health Care Group, L.P.</i> , No. CV 02-4770, 2004 WL 5907538 (C.D. Cal. Jun. 10, 2004).....	19
20	<i>Matter of Wheat Rail Freight Rate Antitrust Litig.</i> , 759 F.2d 1305 (7th Cir. 1985)	14
22	<i>McCagg v. Marquis Jet Partners, Inc.</i> , No. 05 CV 10607, 2007 WL 2454192 (S.D.N.Y. Mar. 29, 2007)	21
24	<i>McCaw Pers. Commc'nns, Inc. v. Pac. Telesis Grp.</i> , 645 F. Supp. 1166 (N.D. Cal. 1986).....	13
25	<i>Mercantile Texas Corp. v. Bd. of Governors of Federal Reserve Sys.</i> , 638 F.2d 1255 (5th Cir. 1981)	22

TABLE OF AUTHORITIES

	Page(s)
1 <i>Nalco Co. v. Turner Designs, Inc.</i> , 2 Case No. 13-cv-02727, 2014 WL 645365 (N.D. Cal. Feb. 19, 2014)	24
3 <i>Pac. Exp., Inc. v. United Airlines, Inc.</i> , 4 959 F.2d 814 (9th Cir. 1992)	8
5 <i>Pace Indus., Inc. v. Three Phoenix Co.</i> , 6 813 F.2d 234 (9th Cir. 1987)	23
7 <i>Pinhas v. Summit Health, Ltd.</i> , 8 894 F.2d 1024 (9th Cir. 1990), <i>aff'd</i> 500 U.S. 322 (1991)	21
9 <i>Pool Water Products v. Olin Corp.</i> , 10 258 F.3d 1024 (9th Cir. 2001)	8
11 <i>Pro Search Plus, LLC v. VFM Leonardo, Inc.</i> , 12 SACV 12-2102-JLS.....	7, 8
13 <i>Putnam v. Putnam Lovell Grp. NBF Securities, Inc.</i> , 14 No. C 05-1330 CW, 2006 WL 1821207 (N.D. Cal. June 30, 2006)	24
15 <i>Re/Max Int'l v. Realty One</i> , 16 173 F.3d 995 (6th Cir. 1999)	17
17 <i>Rebel Oil Co. v. Atl. Richfield Co.</i> , 18 51 F.3d 1421 (9th Cir. 1995)	17, 18, 19
19 <i>Roxane Labs., Inc. v. SmithKline Beecham Corp.</i> , 20 CIV.A. 09-CV-1638, 2010 WL 331704 (E.D. Pa. Jan. 26, 2010)	15
21 <i>Shionogi Pharma, Inc. v. Mylan, Inc.</i> , 22 CIV.A. 10-1077, 2011 WL 3860680 (D. Del. Aug. 31, 2011)	14
23 <i>Solinger v. A & M Records, Inc.</i> , 24 586 F.2d 1304 (9th Cir. 1978)	8, 13
25 <i>Southeast Missouri Hosp. v. C.R. Bard, Inc.</i> , 26 642 F.3d 608 (8th Cir. 2011)	20
27 <i>Stop Youth Addiction, Inc. v. Lucky Stores, Inc.</i> , 28 17 Cal. 4th 553 (1998)	26

Katten
Katten Muchin Rosenman LLP

2029 Century Park East, Suite 2600
Los Angeles, CA 90067-3012
310-383-4400 tel 310-738-4471 fax

TABLE OF AUTHORITIES

		Page(s)
1	<i>Story Parchment Co. v. Paterson Parchment Paper Co.,</i> 282 U.S. 555 (1931).....	12, 16
3	<i>Sullivan v. Tagliabue,</i> 25 F.3d 43 (1st Cir. 1994).....	14
5	<i>Tal v. Hogan,</i> 453 F.3d 1244 (10th Cir. 2006)	14
7	<i>Theme Promotions, Inc. v. News Am. Mktg. FSI,</i> 546 F.3d 991 (9th Cir. 2008)	11
9	<i>Trunov v. Rusanoff,</i> No. 12-CV-04149 NC, 2012 WL 6115608 (N.D. Cal. Dec. 10, 2012)	24
10	<i>United States v. Corinthian Colleges,</i> 655 F.3d 984 (9th Cir. 2011)	25
12	<i>United States v. E. I. du Pont de Nemours & Co.,</i> 351 U.S. 377 (1956).....	17
14	<i>United States v. Marine Bancorporation,</i> 418 U.S. 602 (1974).....	22
16	<i>United States v. Microsoft Corp.,</i> 253 F.3d 34 (D.C. Cir. 2001) (en banc).....	18
18	<i>United States v. Ritchie,</i> 342 F.3d 903 (9th Cir. 2003)	5, 25
20	<i>Verizon Comm'ns Inc. v. Law Offices of Curtis V. Trinko, LLP,</i> 540 U.S. 398 (2004).....	18
22	<i>Williamsburg Wax Museum, Inc. v. Historic Figures, Inc.,</i> 810 F.2d 243 (D.C. Cir. 1987).....	21
24	<i>Xechem, Inc. v. Bristol-Myers Squibb Co.,</i> 372 F.3d 899 (7th Cir. 2004)	14
25	<i>Yellow Pages Cost Consultants, Inc. v. GTE Directories Corp.,</i> 951 F.2d 1158 (9th Cir. 1991)	16

TABLE OF AUTHORITIES

		Page(s)
1	Statutes	
2	15 U.S.C. § 15(a)	7
3	15 U.S.C. § 26.....	7
4	Cartwright Act	26
5	Clayton Act. § 4	7
6	Clayton Act § 7	1, 5
7	Clayton Act § 16	7, 13
8	Rules	
9	Rule 8	24
10	Rule 8(d)	3, 24
11	Rule 12(b)	9
12	OTHER AUTHORITIES	
13	Phillip E. Areeda and Herbert Hovenkamp, Antitrust Law (2008).....	2, 8
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		
26		
27		
28		

1 **I. PRELIMINARY STATEMENT**

2 This case is about a monopolist who controls a life-saving drug with no
 3 meaningful competition. The drug, known as H.P. Acthar Gel (“Acthar”), is needed
 4 by babies who suffer from a rare illness known as Infantile Spasms (“IS”). Without
 5 the drug they may die or face permanent brain damage. Compl. ¶¶ 3, 25. The drug is
 6 also needed by victims of Nephrotic Syndrome (“NS”), a disease that can destroy the
 7 kidneys. *Id.* ¶¶ 3, 30.

8 In the 13 years that Defendant Questcor Pharmaceuticals, Inc. (“Questcor”) has
 9 owned Acthar, it has raised the price from \$50 per vial to over \$28,000 per vial – an
 10 extraordinary exercise of a monopolist’s power. Plaintiff Retrophin, Inc.
 11 (“Retrophin”) sought to break Questcor’s monopoly. It negotiated a deal to purchase
 12 Synacthen, a synthetic ACTH drug that has been used for years outside of the United
 13 States to treat both IS and NS. Retrophin planned to obtain FDA approval for
 14 Synacthen in the US and compete against Acthar in the Relevant Markets defined in
 15 the Complaint. In response, Questcor – acting like a classic monopolist – purchased
 16 Synacthen on the day Retrophin was to close its deal for the product. In so doing,
 17 Questcor foreclosed Retrophin from the market, preserving its monopoly and its
 18 ability to charge extortionate prices. In its motion, Questcor concedes that –
 19 monopolist that it is – it will not seek to introduce Synacthen to treat IS or NS in the
 20 United States. *See* Questcor’s Motion to Dismiss (“Mot.”), at 3-4, 23 (stating that
 21 Questcor is developing Synacthen only for “***new*** indications”).

22 Questcor’s actions constitute: a contract, combination or conspiracy in
 23 unreasonable restraint of trade (Sherman Act Section §1); maintenance and
 24 entrenchment of its monopoly in the Relevant Markets, and/or an attempt to
 25 monopolize those markets with a dangerous probability of success (both in violation
 26 of Sherman Act §2); an acquisition of assets that will result in a substantial lessening
 27 of competition in the Relevant Markets (Clayton Act §7); and a violation of
 28 corresponding provisions of California antitrust law.

Katten
Katten Muchin Rosenman LLP

2029 Century Park East, Suite 2600
Los Angeles, CA 90067-3012
310-788-4400 tel 310-788-4471 fax

1 In its motion to dismiss, Questcor barely mentions these core allegations of
 2 Retrophin's Complaint. It does not dispute the definitions or adequacy of the
 3 Relevant Markets involved, its anticompetitive actions, the prices it charges, or its
 4 intention to prevent Synacthen from competing with Acthar. Instead, Questcor tries to
 5 deflect the Court's attention from its misconduct by raising issues that say little if
 6 anything about Retrophin's claims.

7 In considering Questcor's motion, the late Professor Philip Areeda's adage
 8 about monopolists purchasing competitors bears noting: "a monopolist's acquisition
 9 of a 'likely' entrant into the market in which monopoly power is held is *presumptively*
 10 anticompetitive." Phillip E. Areeda and Herbert Hovenkamp, Antitrust Law, Vol. III
 11 ¶ 701d (2008) (emphasis added). Questcor understands this. Hence it avoids almost
 12 any discussion of the legality of its own conduct.

13 Questcor first argues that Retrophin lacks antitrust injury because it would have
 14 been foreclosed from the Relevant Markets even if a firm other than Questcor had
 15 purchased the rights to Synacthen. That overly simplistic argument does not reflect
 16 Ninth Circuit law, as explained at length by the Court of Appeals in *Glen Holly*
 17 *Entertainment, Inc. v. Tektronix, Inc.*, 352 F.3d 367, 377 (9th Cir. 2003).

18 Second, Questcor asserts that Retrophin lacks antitrust injury because it is
 19 developing its own ACTH drug – RE-034. That Retrophin is attempting to mitigate
 20 its damages by developing its own drug has no bearing on whether it has suffered
 21 antitrust injury. Retrophin's injury – total exclusion or delay in entering the Relevant
 22 Markets – is the heart of antitrust injury.

23 Third, Questcor claims that Retrophin's injury is too speculative to confer
 24 standing because Retrophin has not pled that it "probably" or "likely" would have
 25 obtained FDA approval for Synacthen. The Ninth Circuit imposes no such
 26 requirement, most courts that have addressed the issue at the pleading stage have
 27 rejected it, and Questcor's lead case on this point held that it was error to grant the
 28

1 relief that Questcor seeks here. Finally, it is easy to infer from the Complaint that
 2 FDA approval for Synacthen was likely or probable.

3 Fourth, Questcor asserts that Retrophin fails to plead market or monopoly
 4 power because, contrary to Questcor's statements about the difficulty of obtaining
 5 FDA approval, Retrophin has said that entry into the ACTH markets is "easy" and
 6 that, consequently, barriers to entering the Relevant Markets are low. Putting to one
 7 side the factual inaccuracy of the argument, Questcor completely ignores the fact that
 8 Retrophin pleads *both* direct and circumstantial evidence of market and monopoly
 9 power. The direct evidence of market and monopoly power renders allegations of
 10 entry barriers unnecessary, so Questcor's argument – even if credited – is irrelevant.
 11 In any event, Retrophin's allegations of high entry barriers are more than adequately
 12 pled.

13 Fifth, Questcor raises a finical point about Retrophin's attempt to monopolize
 14 claim, ignoring the fact that the attempt and monopoly maintenance claims are made
 15 in the alternative under Rule 8(d). That is no basis for a motion to dismiss.

16 For the all the reasons set forth above, Questcor's motion should be denied in
 17 its entirety. To the extent any technical amendments are needed, they can readily be
 18 made.

19 **II. STATEMENT OF FACTS**

20 **A. Allegations in the Complaint**

21 This case is about a monopolist that controls a life-saving drug with no
 22 meaningful competition. The drug, Acthar, is needed by babies who suffer from
 23 Infantile Spasms, which can result in death or brain damage. Compl. ¶¶ 3, 25. The
 24 drug is also needed by victims of Nephrotic Syndrome, a disease that can destroy the
 25 kidneys. *Id.* ¶¶ 3, 30.

26 Acthar is controlled by defendant Questcor. It charges \$28,000 for a single
 27 dose of the medicine. Compl. ¶¶ 2, 22, 26, 31, 39, 42, 45. It faces virtually no
 28 competition in the US Relevant Markets defined in the Complaint. *Id.* ¶¶ 35-45.

1 Questcor acquired the rights to Acthar in 2001, when the drug sold for \$50 a vial or
 2 less. *Id.* ¶ 2. Since then, it has ratcheted up the price to \$28,000 a vial – a 56,000%
 3 increase. *Id.* Despite this extraordinary price increase, it has not attracted competition
 4 into the market. *Id.* ¶ 3. This is because Acthar is the only FDA approved long-
 5 lasting therapeutic preparation of adrenocorticotropic hormone (“ACTH”) available to
 6 treat IS and NS in the US.¹ *Id.* ¶¶ 1, 3, 37-45.

7 Synacthen – a synthetic ACTH – is the only other long-lasting ACTH
 8 therapeutic that has been used to treat IS and NS. Compl. ¶¶ 4, 46-47. It has been
 9 sold for decades outside of the US. *Id.* ¶¶ 4, 46. Retrophin planned to acquire
 10 Synacthen, obtain FDA approval for its use, and break Questcor’s monopoly. *Id.* ¶¶
 11 49-52. Between the Summer of 2012 and June 2013, Retrophin engaged in
 12 negotiations with Novartis, Synacthen’s owner, to acquire the rights to manufacture
 13 and sell Synacthen. *Id.* ¶ 11. An agreement on terms was reached, deal documents
 14 were drafted and finalized and were ready for execution. *Id.* A press release
 15 announcing the transaction had been prepared, and June 11, 2013 was set as a
 16 transaction closing date. *Id.*

17 Retrophin had in place a plan for obtaining FDA approval to use Synacthen for
 18 both IS and NS based upon Synacthen’s longstanding track record of both safety and
 19 efficacy. Compl. ¶ 50. Phase I and Phase II clinical trials would not have been
 20 necessary. *Id.*² Retrophin would have begun marketing Synacthen upon its receipt of

21 ¹ In particular, Questcor holds monopoly power in: (a) the market for ACTH
 22 therapeutic drugs (the “ACTH Therapeutic Drug Market”), (b) the market for first-line
 23 drug treatments for IS (the “Infantile Spasms Market”), and (c) the market for
 24 treatments of last resort for NS for those patients who do not respond or cannot
 tolerate primary or secondary treatments for that disease (the “Nephrotic Syndrome
 25 Market”; the ACTH Therapeutic Drug, IS and NS Markets are collectively the
 26 “Relevant Markets”). Compl. ¶¶ 34-45.

27 ² Retrophin also planned to file a Treatment Investigational New Drug Application
 28 which, if approved by the FDA, would have allowed Retrophin to offer Synacthen to
 patients *for free* while it was awaiting FDA approval. Compl. ¶ 50. In other words,
 Synacthen would have immediately undermined Questcor’s monopoly. Questcor’s
 retort that Synacthen could not have obtained such approval (*see* Mot. at 14, n.29) is
 hardly an appropriate issue to resolve on a motion to dismiss. In any event,
 Questcor’s argument is belied by the fact that Acthar is simply not a satisfactory drug
 for large swaths of the relevant populations who, as a result of Questcor’s exorbitant

1 FDA approval for each indication. *Id.* ¶ 51. The result would have been entirely
 2 procompetitive, and would have benefited all market participants – except for
 3 Questcor. *Id.* ¶ 52.

4 Recognizing that Retrophin's acquisition of Synacthen posed a direct threat to
 5 its monopoly, Questcor acted like a classic monopolist – it blocked its rival from
 6 entering the market. Compl. ¶¶ 53-54. On the day Retrophin was to sign its deal
 7 with Novartis, Questcor came in and purchased Synacthen. *Id.* We now know from
 8 Questcor's motion papers that it has put Synacthen on the shelf so that it does not
 9 threaten Acthar's monopoly in IS and NS. *See supra*, at 1 (citing Mot. at 3-4, 23). By
 10 acquiring the rights to exploit Synacthen, Questcor blocked Retrophin from entering
 11 the market, and entrenched its monopoly in violation of Sections 1 and 2 of the
 12 Sherman Act, Section 7 of the Clayton Act, and California State law. Compl. ¶¶ 61-
 13 98.

14 **B. Factual Assertions in Questcor's Motion**

15 Brief mention should be made of some of Questcor's factual statements made
 16 with (or without) citation to materials for which it requests the Court to take judicial
 17 notice.³ To the extent relevant, those points are addressed in the argument section of
 18 Retrophin's Brief. The nature of Questcor's fact arguments are demonstrated by the
 19 following examples. First, Questcor asserts that Retrophin's effort of trying to
 20 develop a Synacthen competitor from scratch, makes it a competitor of Questcor that
 21 is not entitled to relief. *See, e.g.*, Mot. at 10. Questcor then goes on to assert that
 22 Retrophin is such a strong competitor that it claims it will beat Synacthen to market.
 23 *Id.* at 2, 10, 15, 18, 21. Since Questcor admits in its papers that it has no plans to seek
 24

25 price, are forced to either limit their dosages of Acthar to less than the medically
 26 prescribed amount or forgo treatment altogether. Compl. ¶ 52.

27 ³ A document may be incorporated by reference only “*if the plaintiff refers extensively*
 28 *to the document or the document forms the basis of the plaintiff's claim.*” *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003) (emphasis added). Further, a court may *not* take judicial notice of “*disputed facts stated in public records*” on a motion to dismiss because that “*would assume the ‘validity’ of facts ‘yet unproved.’*” *Lee v. City of Los Angeles*, 250 F.3d 668, 689 (9th Cir. 2001).

1 FDA approval for Synacthen for IS and NS, it is tautological that Retrophin will beat
 2 Synacthen to market – assuming it receives FDA approval. *See supra*, at 1 (citing
 3 Mot. 3-4, 23).⁴ Questcor’s point, however, is entirely irrelevant. Whether or not
 4 Retrophin succeeds in gaining approval for RE-034, cannot change the fact that, had it
 5 not been deprived of Synacthen, it would have been far more likely to gain FDA
 6 approval and would have been able to do so faster and more cheaply than it could with
 7 RE-034. Compl. ¶¶ 58-60. It would also have introduced competition to the market
 8 and taken market share and profit from Questcor sooner than otherwise. *Id.* ¶ 61.
 9 Questcor’s effort to deflect attention from that basic fact does nothing to undermine
 10 Retrophin’s case and provides no basis for a 12(b)(6) motion.

11 Second, Questcor asserts that Retrophin is not entitled to antitrust relief because
 12 creating a synthetic ACTH is cheap and easy as evidenced by the “fact” that Retrophin
 13 plans to spend only a total of \$5.0 million to take RE-034 through Phase III clinical
 14 trials for both IS and NS. Mot. at 6-7, 16 (citing Popofsky Decl., Ex. H (Retrophin
 15 Form S-1/A Securities Registration Statement (Jan. 7, 2014) at 219)). Retrophin’s
 16 disclosure was an estimated breakdown of how it would allocate monies it was raising
 17 in a public offering among its various projects. It said nothing about the total cost of
 18 bringing RE-034 to market.

19 Third, Questcor makes much of the fact that other firms are working on
 20 developing ACTH therapies and that, as a consequence, competition is robust in the
 21 Relevant Markets. *See, e.g.*, Mot. at 7. Questcor fails to mention if those firms are
 22 developing products for IS or NS, if they have gone to clinical trials, obtained FDA
 23 approval, or are currently available in the market. This hardly shows robust

24
 25
 26⁴ Similarly baseless is Questcor’s attempt to attribute RE-034’s predicted triumph over
 27 Synacthen to the potential side effects in infants caused by the preservative benzyl
 28 alcohol, which is in Synacthen but not RE-034. Mot. at 15, n.32. As Questcor is
 aware, Synacthen comes with decades worth of safety and efficacy data in IS, giving it
 a dramatic advantage in obtaining FDA approval. *See* Compl. ¶ 59. RE-034 has no
 such data. *Id.* Questcor’s reasoning is also disingenuous, as it has no bearing on
 Questcor’s failure to seek Synacthen’s approval for NS, especially for use in adults.

1 competition or the absence of high entry barriers in the Relevant Markets. They are
 2 meaningless on a motion addressed to the pleading.

3 III. **ARGUMENT**

4 A. **Standards for Motion to Dismiss**

5 In evaluating a motion to dismiss, the court accepts the factual allegations in the
 6 complaint as true, and determines whether they “state a claim to relief that is plausible
 7 on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v.
 8 Twombly*, 550 U.S. 544, 570 (2007)); *Pro Search Plus, LLC v. VFM Leonardo, Inc.*,
 9 SACV 12-2102-JLS ANX, 2013 WL 6229141, at *3-4 (C.D. Cal. Dec. 2, 2013).
 Plaintiff clearly meets that requirement here.

10 B. **Retrophin Alleges Antitrust Injury and Antitrust Standing**

11 Retrophin is entitled to recover treble damages for the injuries alleged in its
 12 Complaint under Section 4 of the Clayton Act. Section 4 provides that any person
 13 “who shall be injured in his business or property by reason of anything forbidden in
 14 the antitrust laws may sue . . . and shall recover threefold the damages by him
 15 sustained, and the cost of suit, including a reasonable attorney’s fee.” 15 U.S.C. §
 16 15(a). Retrophin is also entitled to injunctive relief for its continuing injuries under
 17 Section 16 of the Clayton Act, because it has been foreclosed or, at best, delayed from
 18 entering the Relevant Markets. 15 U.S.C. § 26. Despite this, Questcor seeks
 19 dismissal because it claims that Retrophin does not have “antitrust injury” and because
 20 its injury alleged is too speculative. Neither argument has merit.

21 **1. Retrophin Alleges Antitrust Injury and Threat of Injury.**

22 Questcor’s primary argument is based on the doctrine of antitrust injury – a rule
 23 that prevents antitrust plaintiffs from complaining about an *increase* in competition or
 24 competitively neutral conduct that injures them in the market place. *Brunswick Corp.
 25 v. Pueblo Bowl-O-Mat, Inc.* (“*Brunswick*”), 429 U.S. 477, 484 (1977) (no antitrust
 26 injury where plaintiffs’ “sole injury” was that competitors were able to stay in
 27 business and compete with plaintiffs); *Cargill, Inc. v. Monfort of Colo. Inc.*, 479 U.S.
 28

1 104, 111, 116-17 (1986) (“vigorous competition” does not constitute antitrust injury);
 2 *Pool Water Products v. Olin Corp.*, 258 F.3d 1024, 1035-36 (9th Cir. 2001)
 3 (competitor’s reduced prices did not give rise to antitrust injury); *Pac. Exp., Inc. v.*
 4 *United Airlines, Inc.*, 959 F.2d 814, 818 (9th Cir. 1992).

5 Antitrust injury does not bar recovery where, as here, the plaintiff’s injury
 6 results from a *reduction* in competition. A competitor or potential competitor, such as
 7 Retrophin, that is foreclosed, delayed or otherwise prevented from competing in the
 8 market suffers antitrust injury and has standing to sue under *Brunswick*. 429 U.S. at
 9 489 n.14 (“competitors may be able to prove antitrust injury before they actually are
 10 driven from the market and competition is thereby lessened”); *Gulf States*
 11 *Reorganization Grp., Inc. v. Nucor Corp.*, 466 F.3d 961, 967-68 (11th Cir. 2006)
 12 (potential competitor had antitrust injury when monopolist purchased competitive
 13 assets foreclosing competitor from market); *Glen Holly*, 352 F.3d at 377-78
 14 (competitor foreclosed from market suffered antitrust injury); *In re Dual-Deck Video*
 15 *Cassette Recorder Antitrust Litig.*, 11 F.3d 1460, 1464-65 (9th Cir. 1993) (“*In re*
 16 *Dual-Deck*”) (“even a prospective participant in a market may suffer antitrust injury”)
 17 (quoting *Solinger v. A & M Records, Inc.*, 586 F.2d 1304, 1309 (9th Cir. 1978)); *Pro*
 18 *Search*, 2013 WL 6229141, at *3, 9-10 (denying motion to dismiss where defendant’s
 19 conduct “effectively foreclosed” competitors); Areeda, Volume II, ¶ 35b(a) (potential
 20 competitors have standing to challenge a merger that will exclude them from the
 21 relevant market).⁵

22 Despite the obvious inapplicability of an antitrust injury defense here, Questcor
 23 claims that the “binding authority” of *Lucas Auto. Eng’g, Inc. v.*
 24 *Bridgestone/Firestone, Inc.*, 140 F.3d 1228 (9th Cir 1998), “compels the conclusion
 25 that Retrophin lacks antitrust injury” because Retrophin would have suffered the same

26
 27 ⁵ *Alberta Gas Chemicals Ltd. v. E.I. Du Pont De nemours & Co.*, 826 F.2d 1235 (3d
 28 Cir. 1987) is inapposite. There, the court assumed that Du Pont’s “acquisition [was]
 illegal because it enabled Du Pont to bar Conoco from entering the [market] as an
 independent competitor,” but held Alberta was not injured because it did not allege
 damages as a result of the elimination of potential competition. *Id.* at 1241.

1 injury if someone other than Questcor had purchased Synacthen. Mot. at 9.
 2 Questcor's argument proves too much. If adopted it would mean that, as a matter of
 3 law, an excluded competitor never has standing because something else could have
 4 excluded it from the market. It is thus telling that Questcor nowhere cites the Ninth
 5 Circuit's decision in *Glen Holly*, a case in which the Ninth Circuit explicitly
 6 distinguished *Lucas*, and explained at length how a plaintiff, like Retrophin, who is
 7 foreclosed from competing in the market suffers antitrust injury. 352 F.3d at 377; *see also*
 8 *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 812-13 (D.C. Cir. 2001).

9 Unlike the case here, *Lucas* arose on summary judgment. There, an incumbent
 10 distributor of tires used on vintage or antique automobiles lost a bid to a competing
 11 distributor who became the distributor for all but one of the major vintage tire brands.
 12 140 F.3d at 1230. *Lucas*, the defeated incumbent, sued. It was undisputed that the
 13 winning bidder had not raised prices on its tires after the acquisition, and that *Lucas*
 14 failed to submit a conforming bid for the distribution rights. *Id.* at 1231. Thus, the
 15 court concluded that, under *Brunswick*, *Lucas* had no antitrust injury as a competitor.

16 *Glen Holly*, by contrast, addressed the dismissal of antitrust claims on a Rule
 17 12(b) motion.⁶ There, defendant companies Tektronix and Avid were competitors
 18 who both sold film-editing systems. They entered into a "strategic alliance" whereby
 19 Tektronix stopped manufacturing and selling its system and instead became a
 20 distributor for Avid. 352 F.3d at 368-70. *Glen Holly*, referred to in the opinion as
 21 "Digital Images," was a purchaser of the Tektronix systems. It competed with both
 22 Tektronix and Avid by leasing the Tektronix film editing systems to studios that did
 23 not wish to purchase the systems outright from the defendants. As a result of the
 24 defendants' strategic alliance to stop selling the Tektronix system, *Glen Holly* was no
 25 longer able to compete with the defendants in leasing film-editing equipment and was
 26 forced from the market.

27
 28 ⁶ *Glen Holly* also addressed the dismissal at summary judgment of other non-antitrust
 claims. *See Glen Holly*, 352 F.3d at 368.

1 On a 12(b) motion, the defendants, relying explicitly on *Lucas*, made the
 2 precise argument that Questcor makes here – “antitrust injury [was] not present . . .
 3 because the same harm would have resulted if Tektronix had merely gone out of
 4 business.” *Id.* at 372. The Ninth Circuit flatly rejected the argument and reversed the
 5 district court’s dismissal of plaintiff’s antitrust claims. It held, after an extended
 6 discussion of the antitrust injury case law, that the plaintiff sufficiently stated antitrust
 7 injury. *Id.* at 377. In language that directly rejects Questcor’s motion and its reliance
 8 on *Lucas*, the Court wrote:

9 This case at this stage is not *Brunswick*, it is not *Cargill*, it is not *Pool*
 10 *Water*, and it is not *Lucas Automotive*. In the *Brunswick* line of cases, the
 11 alleged “injury” was simply a loss of greater profits caused by *increased*
 12 competition stemming from the alleged wrongful acts. Here, as the
 13 record now stands, there is *no* pro competitive aspect of the defendant’s
 14 strategic alliance, none.

15 *Id.* at 377 (emphasis added). The Court went on to reject the specific argument
 16 Questcor advances here:

17 [W]hatever might have happened to Digital Images, had some other
 18 event occurred resulting in the demise of Lightworks, *is irrelevant* in this
 19 context. The strategic alliance set out to exterminate Lightworks and
 20 allegedly succeeded, leaving only one product, no choices, and no
 21 competition in its wake.

22 *Id.* (emphasis added); *see also Theme Promotions, Inc. v. News Am. Mktg. FSI*, 546
 23 F.3d 991, 1003 (9th Cir. 2008) (citing to *Glen Holly*). That is exactly the case here.
 24 *See Compl. ¶¶ 46-56, 61-63. Lucas provides no basis for dismissal.*⁷

25
 26 ⁷ Questcor cites to inapposite cases where the injury was a result of third-parties, not
 27 defendant. *See, e.g., City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 268 (3d
 28 Cir. 1998) (“statutory scheme precluded competition” not defendant’s conduct); *Axis,
 S.p.A. v. Micafil, Inc.*, 870 F.2d 1105 (6th Cir. 1989) (no antitrust injury because
 “[plaintiff’s] exclusion from the [market] did not result from . . . [defendant’s]
 anticompetitive act,” but rather was a result of conduct by third-parties).

1 Questcor's remaining argument on antitrust injury is that Retrophin has not
 2 been injured because it is currently seeking an alternative entry path to the market
 3 with RE-034. According to Questcor, since Retrophin complains that Questcor's
 4 acquisition of Synacthen is anticompetitive because it shields Acthar from
 5 competition, Retrophin's acquisition of Synacthen would be equally anticompetitive
 6 because it would shield RE-034 from competition. The argument is not credible.

7 Questcor cannot equate Acthar, a monopoly drug sold for \$28,000 a vial, with
 8 RE-034 – a drug that is under development, has never been sold and, indeed, as of this
 9 writing has not yet been injected into a human being.⁸ Questcor's acquisition of
 10 Synacthen results in antitrust injury because it shields Acthar from the competitive
 11 threat that Synacthen presents in the hands of Retrophin. Retrophin's ownership of
 12 Synacthen only has a *positive* competitive effect because it breaks the Acthar
 13 monopoly and would speed Synacthen's entry into the Relevant Markets. It has no
 14 anticompetitive effect with respect to RE-034 because RE-034 at this time has zero
 15 sales, zero market share, zero market presence and, indeed, cannot be sold legally in
 16 the US, or anywhere else. Questcor's argument is meritless.⁹

17 **2. Retrophin Alleges Antitrust Standing**

18 Questcor also contends that Retrophin lacks standing because it fails to satisfy
 19 only one of the several criteria considered in evaluating antitrust standing – a non-
 20 speculative injury. *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of*
Carpenters, 459 U.S. 519, 536-37 (1983) (standing is not a “black-letter rule” instead
 21 various factors are considered). Questcor is wrong on both the law and the facts. The
 22

23
 24 ⁸ For the same reason, Questcor's claim that Retrophin “began pursuing” RE-034
 25 before Novartis licensed Synacthen to Questcor is irrelevant. Mot. at 16. Moreover, it
 26 is plain from the documents Questcor cites (*see id.* at 16, 16 n.38) that Retrophin had
 27 to investigate product sourcing and the like, whether it purchased Synacthen or
 28 developed its own alternative ACTH.

29 ⁹ Questcor's assertion that RE-034 will beat Synacthen to the market is a red herring.
 To preserve its monopoly in the Relevant Markets, Questcor has purposefully *not*
 pursued those markets with Synacthen. If it obtains FDA approval, RE-034 will
 necessarily win the race since Questcor has chosen not to race with Synacthen at all.
See supra, at 1 (citing Mot. at 3-4, 23).

1 Supreme Court has held that where, as here, a plaintiff is deprived of access to a key
 2 good that is necessary for him to compete, his injury is not speculative whether he is
 3 totally prevented or simply delayed from competing in the market. *Bigelow v. RKO*
 4 *Radio Pictures*, 327 U.S. 251, 255-57, 265-66 (1946); *Story Parchment Co. v.*
 5 *Paterson Parchment Paper Co.*, 282 U.S. 555, 560, 567 (1931). The chain of the
 6 plaintiff's causation must be far more complex and indirect for it to be unduly
 7 speculative. That occurred, for example, where a plaintiff labor union – which was
 8 neither a consumer or competitor in the relevant market – claimed injury because a
 9 group of contractors decided to boycott union subcontractors in favor of non-union
 10 contractors with the alleged result that demand for union labor fell and that the union
 11 was somehow injured as a result. *Associated Gen. Contractors of Cal., Inc.*, 459 U.S.
 12 at 540-44. The Supreme Court held that chain of causation was so long, indirect, and
 13 complex that the Union's injury was too speculative and remote to be compensable.
 14 *Id.* That is hardly the case here.

15 When these principles were applied in Questcor's lead case, *Andrx*
 16 *Pharmaceuticals*, the court ruled that a drug maker which, like Retrophin, was
 17 delayed in bringing a drug to market by defendants' anticompetitive conduct, was able
 18 to plead injury that was *not* speculative. All it had to plead was its intent and
 19 preparedness to enter the market. 256 F.3d 799, 806-07. This is in accord with Ninth
 20 Circuit law. *See, e.g., Bubar v. Ampco Foods, Inc.*, 752 F.2d 445, 450 (9th Cir. 1985)
 21 (citing *Solinger*, 586 F.2d at 1304, 1309-10); *In re Dual-Deck*, 11 F.3d at 1464-65. It
 22 is worth noting that, in the Ninth Circuit, this test is "factual in nature and seldom
 23 presents a situation appropriate for a determination by summary judgment," let alone a
 24 motion to dismiss. *Solinger*, 586 F.2d at 1310.¹⁰ In any event, there can be no dispute

25
 26¹⁰ *See also Chelson v. Oregonian Pub. Co.*, 715 F.2d 1368, 1370-71 (9th Cir. 1983)
 27 (reversing grant of summary judgment for lack of antitrust standing where plaintiffs
 28 were "neither consumers nor competitors in the relevant market" but they
 demonstrated "the requisite intention and preparedness to expand [into the market]");
McCaw Pers. Commc'nns, Inc. v. Pac. Telesis Grp., 645 F. Supp. 1166, 1170 (N.D. Cal. 1986) (denying summary judgment and finding that plaintiff has standing as a prospective purchaser under § 16 of the Clayton Act based on its intent and

1 that Retrophin meets this standard because it alleged facts in its Complaint on its
 2 background, preparation, financial capacity, and consummation of contracts. Compl.
 3 ¶¶ 50-52. Indeed, Questcor admits that Retrophin *does* have the intent and
 4 preparedness to enter the market with the unproven RE-034 – an entry process that
 5 Questcor repeatedly characterizes as “easy.” Mot. at 16.¹¹ If, according to Questcor,
 6 entering with RE-034 – a brand new drug that has never been tested or used on
 7 humans – is “easy,” entering with Synacthen, a drug that has been used around the
 8 world for decades, should be a slam dunk.

9 Notwithstanding the foregoing, all of which warrants a flat rejection of
 10 Questcor’s speculative injury claim, Questcor insists that “as a matter of law”
 11 Retrophin’s injury is too speculative because it hasn’t pled that it would “probably”
 12 have obtained FDA approval for Synacthen had it acquired it and therefore, the
 13 Complaint should be dismissed *with prejudice*. Mot. at 12. The argument is baseless.

14 First, Questcor cites no Ninth Circuit authority that a drug maker must plead
 15 “probable” or “likely” FDA approval in order to establish standing. Second, other
 16 courts that have considered the significance of FDA approval merely view it as one
 17 factor, among others, in considering intent and preparedness and have *denied* motions
 18 to dismiss where arguments like Questcor’s have been raised. *See Xechem, Inc. v.*
 19

20 preparedness to enter the paging business).

21 ¹¹ Questcor cites to inapplicable cases that did not involve the plaintiff’s exclusion as a
 22 competitor from the market as a result of defendant’s conduct. *See Tal v. Hogan*, 453
 23 F.3d 1244, 1258 (10th Cir. 2006) (third-party potential buyer); *Sullivan v. Tagliabue*,
 24 25 F.3d 43, 51-52 (1st Cir. 1994) (third-party potential seller); *Antoine L. Garabet,*
 25 *M.D., Inc. v. Autonomous Technologies Corp.*, 116 F. Supp. 2d 1159, 1166-67 (C.D.
 26 Cal. 2000) (third-party’s reduced market share); *Broadcom Corp.*, 501 F.3d at 315-20
 27 (no allegation plaintiff “will seek to enter the . . . markets”); *AMA v. United*
 28 *Healthcare Corp.*, No. 00 Civ. 2800 (LMM), 2007 WL 683974, at *6 (S.D.N.Y Mar.
 5, 2007) (third party physicians’ illegal acts would result in the injury); *Matter of*
Wheat Rail Freight Rate Antitrust Litig., 759 F.2d 1305, 1307, 1313-14 (7th Cir.
 1985) (injurious rate approved by the Interstate Commerce Commission, not
 defendants). In *Carefusion Corp. v. Medtronic, Inc.*, the court found that
 “Defendants’ removal of product lines after [a] merger may constitute anticompetitive
 conduct. 10-CV-01111-LHK, 2010 WL 4509821, at *9 (N.D. Cal. Nov. 1, 2010).
 There, however, the court found that plaintiff’s delay of entry into the market was
 based on plaintiff’s own “business decision,” rather than defendant’s “unlawful”
 conduct. *Id.*

Bristol-Myers Squibb Co., 372 F.3d 899, 900, 902 (7th Cir. 2004) (F. Easterbrook, D. Wood on the panel) (denying motion to dismiss, even though plaintiff had not filed an application with the FDA); *Shionogi Pharma, Inc. v. Mylan, Inc.*, CIV.A. 10-1077, 2011 WL 3860680, at *6-7 (D. Del. Aug. 31, 2011) (denying motion to dismiss where plaintiff had not received FDA approval); *Roxane Labs., Inc. v. SmithKline Beecham Corp.*, CIV.A. 09-CV-1638, 2010 WL 331704, at *4 (E.D. Pa. Jan. 26, 2010) (denying motion to dismiss).

Third, not even *Andrx* supports Quesctor’s argument. *Andrx* held that it was error to dismiss the defendant’s antitrust counterclaim with prejudice on grounds of speculative injury – the exact relief Questcor seeks here. 256 F.3d at 808. Fourth, the *Andrx* court explained that the defendant could readily plead on its counterclaim that it would “probably” receive FDA approval based on the facts pled and because *Andrx* had acted in a way that showed its expectation that Biovail, the counter-claimant, *would* get FDA approval. The facts here are quite similar. Synacthen has been used successfully to treat IS and NS in dozens of countries outside of the US for decades. Compl. ¶ 59. The owner of the Synacthen rights has decades of safety and efficacy data to speed approval through the FDA. *Id.* And Questcor has acted as if it fears a FDA approved Synacthen in the hands of Retrophin. If this Court wants to make law in the Ninth Circuit and require, contrary to the courts in other circuits, that Retrophin must plead that it is “probable” or “likely” that it would have received FDA approval for Synacthen, it is easy to infer that allegation from the facts in the Complaint described above. It is equally easy to cure by amendment. In any event, far from justifying dismissal of Retrophin’s case with prejudice, *Andrx* is direct support for denying Questcor’s motion.¹²

¹² The other cases on which Questcor relies do not come close to the factual allegations pleaded by Retrophin. See *Brotech Corp. v. White Eagle Int'l Technologies Grp., Inc.*, CIV.A.03-232, 2004 WL 1427136, at *5-6 (E.D. Pa. June 21, 2004) (granting motion to dismiss “without prejudice” where plaintiff’s complaint contained no facts indicating plaintiff’s intent to enter the medical device market); *Bristol-Myers Squibb Co. v. Copley Pharm., Inc.*, 144 F. Supp. 2d 21, 25 (D. Mass. 2000) (granting motion to dismiss for lack of standing without prejudice).

1 Questcor's remaining attempts to cast Retrophin's injury as speculative are
 2 based on the two erroneous assumptions that: (1) Novartis allegedly would not have
 3 sold Synacthen to Retrophin; and (2) Retrophin has a more promising path to market
 4 with RE-034 than it did with Synacthen. Mot. at 12-15.

5 First, Retrophin unequivocally alleged that Novartis would have sold Synacthen
 6 to Retrophin absent Questcor's misconduct. The final documents were prepared and
 7 the signing was set for June 11, 2013. Compl. ¶ 49. A press release had already been
 8 prepared announcing the deal. *Id.* The *very same day* Novartis was to close its deal
 9 with Retrophin, Questcor swooped in and acquired the rights. *Id.* ¶ 54. Questcor does
 10 not and cannot deny these allegations. Its assertion that this link in showing
 11 Retrophin's injury is speculative is not credible.

12 Second, Questcor's claim that Retrophin's injury is speculative because it has
 13 an alternative route to market through RE-034 is simply wrong. At best, Questcor's
 14 illegal conduct has delayed, and increased the cost of, Retrophin's entry into the
 15 relevant markets. Compl. ¶¶ 57-63. At worst, its conduct has precluded Retrophin
 16 from the market completely. *Id.* In either scenario, Retrophin has clearly been
 17 damaged. The only issue is a factual one – the precise dollar amount of Retrophin's
 18 injury. The Supreme Court has made it abundantly clear that once an antitrust victim
 19 has demonstrated the fact of its injury, the amount of its damage is to be left to the
 20 jury by fair and reasonable estimate. *Bigelow*, 327 U.S. at 264 ("jury may make a just
 21 and reasonable estimate of the damages based on relevant data"); *Story Parchment
 22 Co.*, 282 U.S. at 563 ("[I]t will be enough if the evidence show[s] the extent of the
 23 damages as a matter of just and reasonable inference, although the result be only
 24 approximate"); *Yellow Pages Cost Consultants, Inc. v. GTE Directories Corp.*, 951
 25 F.2d 1158, 1163 (9th Cir. 1991) (same).

26 Accordingly, Questcor's argument that Retrophin lacks antitrust standing is
 27 meritless. To the extent its nitpicking warrants amendment, those amendments can
 28 easily be made.

1 **C. Retrophin Alleges Market and Monopoly Power and Harm to**
 2 **Competition**

3 Questcor also challenges Retrophin's Complaint for failing to plead market and
 4 monopoly power and harm to competition. Questcor's argument is based on two
 5 flatly inconsistent positions. First, it argues that it has no market or monopoly power
 6 because Retrophin supposedly faces no barriers to entry since it hopes to seek FDA
 7 approval for RE-034. Questcor then completely reverses field and asserts that no
 8 single potential competitor is likely to obtain FDA approval, rendering any
 9 competitive injury speculative. As a matter of logic and law, Questcor is wrong on
 both counts.

10 **1. Retrophin Alleges Market and Monopoly Power.**

11 The Supreme Court defines market and monopoly power as "the power to
 12 control prices or exclude competition." *United States v. E. I. du Pont de Nemours &*
Co., 351 U.S. 377, 391 (1956). There are two ways to prove such power – directly or
 13 circumstantially. *See Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir.
 14 1995). Where direct evidence is available, there is no need for circumstantial
 15 evidence. *Id.*; *Image Technical Servs. v. Eastman Kodak Co.*, 125 F.3d 1195, 1202
 16 (9th Cir. 1997). Here, Retrophin has pled *both*. Compl. ¶¶ 2, 22-23, 26-28, 31-33, 35-
 17 45. Questcor, however, has only attacked one element of the circumstantial evidence
 18 allegations – high barriers to market entry – and has carefully avoided Retrophin's
 19 allegations of direct evidence. Accordingly, Questcor's attack is fundamentally
 20 flawed. Even if everything Questcor says about entry barriers is correct (and it is
 21 manifestly not), Retrophin still pleads market and monopoly power on the basis of
 22 direct evidence. This portion of Questcor's motion thus provides no basis for a
 23 dismissal.

24 Evidence of anticompetitive effects, such as restricted output and
 25 supracompetitive prices, or actual exclusion of competitors constitutes direct
 26 evidence of market and monopoly power. *See Rebel Oil*, 51 F.3d at 1434; *Re/Max*
Int'l v. Realty One, 173 F.3d 995, 1016, 1018-20 (6th Cir. 1999) (direct evidence is

1 “actual control over prices or the actual exclusion of competitors”); *Broadcom Corp.*,
 2 501 F.3d at 307; *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001)
 3 (en banc).

4 Retrophin pled such evidence here. When Questcor acquired the rights to
 5 Acthar in 2001 it was selling for \$50 per vial. Compl. ¶ 2. Since then, Questcor has
 6 systematically raised the price to \$28,000. *Id.* ¶¶ 2, 22, 26, 31, 39, 42, 45. Despite
 7 those extortionate prices, no new competitors have entered the market for over a
 8 dozen years. Absent monopoly power, they clearly would have. *See Verizon*
 9 *Comm’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004)
 10 (“The opportunity to charge monopoly prices – at least for a short period – is what
 11 attracts ‘business acumen’ in the first place”). When Retrophin tried to enter the
 12 market by acquiring Synacthen, Questcor intentionally blocked its entry. Compl. ¶¶
 13 53-56. These allegations are more than sufficient to establish market and monopoly
 14 power directly. *See Am. Tobacco Co. v. United States*, 328 U.S. 781, 789 (1946)
 15 (intentional exclusion of some competitors supported jury’s monopolization finding);
 16 *In re ATM Fee Antitrust Litig.*, No. C 04-2676, 2010 WL 2557519, at *10 (N.D. Cal.
 17 Jun. 21, 2010) (strong indication of market power where prices exist above the
 18 competitive level without erosion by new entry or expansion). Questcor says nothing
 19 about the adequacy of these allegations to establish market or monopoly power in its
 20 motion. This element of Retrophin’s Complaint is thus clearly pled and unchallenged
 21 by Questcor.

22 Questcor similarly fails meaningfully to challenge Retrophin’s circumstantial
 23 evidence. In order to allege market or monopoly power circumstantially, a complaint
 24 must plead: (1) the relevant markets, (2) the monopolist’s dominant shares in those
 25 markets, and (3) significant barriers to entry and the inability of competitors to
 26 increase their output in the short run. *Rebel Oil*, 51 F.3d at 1434. The Complaint
 27 satisfies these criteria. Retrophin alleges the existence of three relevant product and
 28 geographic markets, dominant positions in those markets, and significant barriers to

entry. Compl. ¶¶ 19-45. Questcor's only challenge is to the third item – barriers to entry. Retrophin alleges three separate barriers to entry – the difficulty of developing a new product, Questcor's orphan drug designation for Acthar which bars other chemically identical drugs from being offered to victims of Infantile Spasms, and the need for FDA approval. Compl. ¶¶ 22-23, 26-28, 31-33. Questcor concedes the first two and only challenges the third – the need for FDA approval. According to Questcor, FDA approval for Synacthen “is not a legally cognizable entry barrier” because every firm, including incumbent Questcor, had to meet the same FDA approval requirements. Mot. at 18. According to Questcor “[e]ntry barriers are ‘additional long-run costs that were not incurred by incumbent firms but must be incurred by new entrants.’” *Rebel Oil*, 51 F.3d at 1439 (citation omitted).

The argument is wrong as a matter of fact and law. It is wrong as a matter of fact because, to this day, Questcor admits that it has not sought FDA approval for Synacthen for IS or NS. *See supra*, at 1 (citing Mot. at 3-4, 23). It is also wrong on the law. In language Questcor chose not to cite in *Rebel Oil* the Ninth Circuit explicitly held that legal requirements clearly constitute entry barriers.

The main sources of entry barriers are: (1) legal license requirements; (2) control of an essential or superior resource; (3) entrenched buyer preferences for established brands; (4) capital market evaluations imposing higher capital costs on new entrants; and, in some situations, (5) economies of scale. *In evaluating entry barriers, we focus on their ability to constrain not those already in the market, but . . . those who would enter but are prevented from doing so.*

Rebel Oil, 51 F.3d at 1439 (citations and quotations omitted) (emphasis added). Indeed, the requirement of FDA approval has been found time and again to constitute a barrier to entry. *See, e.g., Masimo Corp. v. Tyco Health Care Group, L.P.*, No. CV 02-4770, 2004 WL 5907538, at *4 (C.D. Cal. Jun. 10, 2004) (barriers to entry included “significant up-front costs and lead times . . . to obtain FDA approval”); *see*

1 also *Southeast Missouri Hosp. v. C.R. Bard, Inc.* 642 F.3d 608, 623 (8th Cir. 2011)
 2 (“[A] lengthy and burdensome FDA review process exists as an entry barrier”).

3 Questcor also argues that out-of-context, selective quotations from Retrophin’s
 4 public statements preclude it from asserting high barriers to entry because other drug
 5 developers are working on ACTH products. Mot. at 18-19. Questcor leaps to this
 6 conclusion without identifying a single drug that has been approved by the FDA, a
 7 single drug other than RE-034 - that is intended to treat victims of IS and NS, a single
 8 drug that is on the market, or a single drug that has caused Questcor to drop the price
 9 of Acthar from \$28,000/dose. The mere fact that others are trying to develop
 10 synthetic ACTH products cannot undermine the two basic facts in the Complaint that
 11 Questcor avoids altogether – it has a drug that treats fatal and debilitating diseases and
 12 it has such an air tight monopoly that it can charge \$28,000 a dose. Compl. ¶¶ 2, 22,
 13 26, 31, 39, 42, 45. These allegations amply demonstrate that Questcor is a monopolist
 14 and holds both market and monopoly power.

15 2. **Retrophin Alleges Harm to Competition.**

16 Questcor also argues that Retrophin merely alleges a speculative injury to
 17 competition because there is no allegation that Synacthen is “likely” to be approved
 18 by the FDA and that such an injury is not cognizable under applicable case law. This
 19 argument is essentially a repetition of its earlier argument that FDA approval is an
 20 insuperable barrier to entry. Mot. at 17-19. It can be rejected for the same reasons
 21 outlined above at pp 12-14.

22 Putting to one side that Questcor’s argument here flatly contradicts its prior
 23 argument that entry into the Relevant Markets is easy, Questcor ignores the clear
 24 allegations of the Complaint. Retrophin was poised and ready to acquire rights to
 25 Synacthen, use Synacthen’s decades of clinical and efficacy data to speed the FDA
 26 approval process and take market share from Questcor by charging a fraction of the
 27 price that Questcor charges for Acthar. Compl. ¶¶ 46-52, 59. Questcor thwarted this
 28 direct challenge to its monopoly. *Id.* ¶¶ 5-6, 53-54. Questcor admits as much when it

1 says it is *not* seeking FDA approval for Synacthen for IS or NS – assuring that
 2 Synacthen would not challenge Acthar's monopoly in the Relevant Markets. *See*
 3 *supra*, at p. 1.

4 Foreclosure of entry to the market is an injury to competition when it results in
 5 higher prices or poorer choices for consumers. *See Pinhas v. Summit Health, Ltd.*,
 6 894 F.2d 1024, 1032 (9th Cir.1990), *aff'd* 500 U.S. 322 (1991) ("[P]reclusion of
 7 [plaintiff] from practicing could conceivably injure competition by allowing other[s]
 8 . . . to charge higher prices for their services."); *Allied Orthopedic Appliances Inc. v.*
 9 *Tyco Health Care Group LP*, 592 F.3d 991, 996 n.1 (9th Cir. 2010) (violation may be
 10 found where an agreement has the probable or actual effect of foreclosing
 11 competition); *McCagg v. Marquis Jet Partners, Inc.*, No. 05 CV 10607, 2007 WL
 12 2454192, at *3-4 (S.D.N.Y. Mar. 29, 2007) (foreclosure of potential competitor from
 13 market is an injury to competition). That has clearly occurred here.¹³

14 Questcor's second argument, that Retrophin could not plead an injury to
 15 competition because Novartis – the seller of Synacthen – was one of a handful of
 16 potential entrants, also lacks merit. Questcor cites three cases for the proposition, but
 17 none of them come close to supporting its position. Those cases involve highly
 18 competitive markets with many competitors or potential competitors. They stand for
 19

20 ¹³ Questcor's position is not helped by its citation to *In re Relafen Antitrust Litig.*, 286
 21 F. Supp. 2d 56 (D. Mass. 2003). That case involved the question of when the statute
 22 of limitations should begin to run in a consumer class action based on a claim of
 23 "sham litigation" brought by the defendant to block the introduction of a generic drug
 24 in the market. That statute of limitations holding provides no guidance as to whether
 25 Retrophin's injury is speculative here, especially since the court went out of its way to
 26 distinguish the case of a consumer class action from a lawsuit filed by a competitor
 27 who was excluded from the market, when it acknowledged that "lack of FDA
 28 approval did not bar an antitrust suit brought by a generic drug competitor" *Id.* at 63
 (citing and distinguishing *Andrx*). Questcor's other authority, *West Penn Power*, is
 equally unavailing. There, the court recognized that "[t]he Supreme Court has made
 clear that regulated industries – even those that historically have been treated as
 natural monopolies – are not exempt from the antitrust laws." 147 F.3d at 263. In
West Penn Power, however, the regulatory scheme was so comprehensive that it
 mandated that the merging entities not compete. *Id.* at 265-66. Here, there is no such
 regulation. In its attempt to purchase Synacthen, Retrophin was prepared to comply
 with FDA regulations, clear those hurdles and enter the market. *See supra*, at pp. 4-5;
 Compl. ¶¶ 50-51.

1 the unremarkable proposition that foreclosure of a single competitor from a
 2 competitive market containing many firms is not anticompetitive. That is manifestly
 3 not the case here. *See Mot.* at 20 citing *Mercantile Texas Corp. v. Bd. of Governors of*
Federal Reserve Sys., 638 F.2d 1255, 1267 (5th Cir. 1981) (“If there are numerous
 4 potential competitors waiting in the wings, elimination of Mercantile as one potential
 5 entrant would not be significant.”); *FTC v. Atl. Richfield Co.*, 549 F.2d 289, 300 (4th
 6 Cir. 1977) (foreclosure not anticompetitive where 86 other firms were developing
 7 similar products, and seven other firms had entered the market within ten years); *In re*
8 Champion Spark Plug Co., 103 F.T.C. 546, 631, 1984 WL 565371, at *65 (1984)
 9 (elimination of potential entrant where seven firms entered markets with low barriers
 10 to entry in recent years); *see also United States v. Marine Bancorporation*, 418 U.S.
 11 602, 625 (1974) (finding on the narrow, and immaterial issue of whether prior law
 12 “proscribes a market extension merger solely on the ground that such a merger
 13 eliminates the prospect for long-term deconcentration of an oligopolistic market that
 14 in theory might result if the acquiring firm were forbidden to enter except through a de
 15 novo undertaking”). Here, Questcor is the *only* company that sells an ACTH drug for
 16 therapeutic purposes. Compl. ¶¶ 37-39. Currently, there are only two ACTH drug
 17 therapies in use: Acthar and Synacthen. *See id.* ¶¶ 1, 46-54. As a result of
 18 Questcor’s anticompetitive acquisition, it now owns both and it has put Synacthen on
 19 the shelf so that it will not threaten Acthar’s monopoly position in the Relevant
 20 Markets. *See supra* at pp. 1, 3-5. The injury to competition could not be more plain.

21 Finally, Questcor argues that any injury to competition is transient, in light of
 22 the number of ACTH drugs in development. None of those drugs is in the market and
 23 it is unclear if they ever will be. What is clear is that Acthar has had a monopoly in
 24 the US for more than a decade – that is hardly transient. *See Compl.* ¶¶ 1-2. If
 25 Retrophin succeeds in gaining FDA approval for RE-034, hardly a foregone
 26 conclusion, Questcor’s monopoly continues through the approval process. That is not
 27 transient either. Not surprisingly, Questcor fails to cite to any authority holding that

foreclosure from the market for an indefinite period is not an injury to competition. Instead, its primary support is a summary judgment case, *Adaptive Power Solutions, LLC v. Hughes Missile Sys. Co.*, in which a four to ten months reduction in competition was deemed to be a *de minimis* injury to competition.¹⁴ 141 F.3d 947, 951-52 (9th Cir. 1998). Here, the injury to the market will endure for as long as Questcor maintains its monopoly in the Relevant Markets. There is no time limit on that maintenance because there is no guarantee that Retrophin will ever have the ability to enter the markets. That is made clear in Retrophin's Complaint. Compl. ¶ 60. Even if Retrophin ultimately enters the market with RE-034, delayed entry constitutes an injury under the antitrust laws. See *Bigelow*, 327 U.S. at 255-66; *Pace Indus., Inc. v. Three Phoenix Co.*, 813 F.2d 234, 240 (9th Cir. 1987); *Andrx*, 256 F.3d at 814-816.

D. Retrophin Alleges an Attempt to Monopolize Claim

Questcor erroneously argues that Retrophin fails to plead an attempt to monopolize claim because "there is no such thing as attempted maintenance of monopoly power, only attempted attainment." Mot. at 22. Under Federal Rule of Civil Procedure 8(d), Retrophin is permitted to plead in the alternative. Retrophin has

¹⁴ Questcor cites four other cases in support of its argument that Retrophin's injury is too transient to constitute an injury to competition. They are inapposite. In *American Professional Testing Service, Inc. v. Harcourt Brace Jovanovich Legal & Professional Publications, Inc.*, the Ninth Circuit required a showing of "more than temporary" harmful effects to competition in cases in which the conduct alleged was disparagement of a rival or compromising a rival employee. 108 F.3d 1147, 1151 (9th Cir. 1997). In *Borough of Lansdale v. Philadelphia Elec. Co.*, the court, affirming a jury verdict, concluded that the record before it lacked evidence of monopoly power or that the entry of a competitor was "economically []realistic." 692 F.2d 307, 313-14 (3d Cir. 1982). The court did not base its decision on the transient nature of the injury to competition. *Id.* Finally, Questcor cites to *Apex Oil Co. v. DiMauro*, but that case did not focus on an injury to competition at all; instead, the court addressed whether the defendants possessed a specific intent to monopolize and held that their conduct led to "no more than a few business days" in which they held an unfair competitive advantage. 713 F. Supp. 587, 600-01 (S.D.N.Y. 1989). A few business days pales in comparison to the indefinite delay in Retrophin's entry to the Relevant Markets. *Williamsburg Wax Museum, Inc. v. Historic Figures, Inc.*, 810 F.2d 243 (D.C. Cir. 1987) concerned a consumer plaintiff who was forced to obtain services of a competitor of the defendant, that provided services slower than the defendant. That is not the case here where Questcor remains the sole participant in the market.

1 done so. It can, and has, pled monopolization and attempted monopolization of each
 2 of the three Relevant Markets in the alternative.¹⁵ If, for some reason, Retrophin's
 3 monopoly maintenance claims fail, it is still free to pursue its attempt claims. Relying
 4 on the alternative pleading principle in Rule 8 is hardly a basis for a 12(b)(6) motion
 5 to dismiss. *See Putnam v. Putnam Lovell Grp. NBF Securities, Inc.*, No. C 05–1330
 6 CW, 2006 WL 1821207, at *7 (N.D. Cal. June 30, 2006) (denying motion to dismiss
 7 because “plaintiffs are allowed to plead mutually exclusive claims in the alternative”);
 8 *Trunov v. Rusanoff*, No. 12–CV–04149 NC, 2012 WL 6115608, at *3 (N.D. Cal. Dec.
 9 10, 2012) (same); *F.D.I.C. v. Faigin*, No. CV 12–03448, 2013 WL 3389490, at *10
 10 (C.D. Cal. July 8, 2013) (same).

11 As for Questcor's confusing objections to the market shares alleged by
 12 Retrophin for the Relevant Markets, Questcor again ignores the direct evidence of
 13 monopoly power that establishes the basis for Retrophin's claims of monopolization
 14 and attempted monopolization. Moreover, Ninth Circuit case law is clear that there is
 15 no market share too high to allege an attempt to monopolize claim, so long as there is
 16 “a dangerous probability of achieving monopoly.” *See Nalco Co. v. Turner Designs,*
 17 *Inc.*, Case No. 13-cv-02727, 2014 WL 645365, at *9 (N.D. Cal. Feb. 19, 2014)
 18 (denying motion to dismiss attempt to monopolize claim where defendant was alleged
 19 to have a 90% market share and engaged in anticompetitive conduct to increase
 20 market share). Any dispute as to whether a “dangerous probability” of success in
 21 monopolization exists is a question of fact that is not appropriate to resolve on a
 22 motion to dismiss. *See Broadcom Corp.*, 501 F.3d at 318.

23 **E. Retrophin Alleges an Absence of Business Justifications**

24 Questcor also argues that its successful effort to foreclose Retrophin from the
 25 relevant markets should be excused because it claims to have procompetitive business
 26 justifications for acquiring Synacthen. Mot. at 23. Those procompetitive business
 27

28 ¹⁵ Retrophin pleads that Questcor possesses 100% of the ACTH Therapeutic Drug
 Market (Compl. ¶ 39), more than 50% of the Infantile Spasm Market (*id.* ¶ 42), and
 the dominant share in the Nephrotic Syndrome Market (*id.* ¶ 43).

1 justifications are disputed, not alleged in the Complaint and therefore cannot be
 2 considered on a motion to dismiss.¹⁶ Indeed, Retrophin explicitly alleges that there
 3 are *no* procompetitive business justifications for Questcor's acquisition of Synacthen.
 4 Compl. ¶ 63. Questcor argues that Retrophin's allegation in this regard is
 5 "conclusory," but completely ignores Retrophin's explicit allegations of the
 6 anticompetitive rationale for Questcor's conduct. Retrophin's approach was certainly
 7 sufficient for the Court of Appeals in *Glen Holly*. 343 F.3d at 1013-15 (finding no
 8 procompetitive justification).

9 Perhaps recognizing that its claim of conclusory allegations is insufficient,
 10 Questcor seeks to manufacture a business justification by claiming that it is
 11 developing Synacthen and obtaining FDA approval for *new* indications – illnesses
 12 other than IS and NS, two of the three Relevant Markets identified in the Complaint.
 13 Mot. at 23. This argument is meritless. Questcor has had the ability *for years* to seek
 14 FDA approval for the indications that it now claims to be investigating for Synacthen.
 15 Questcor could have sought approval for these indications with Acthar – the drug it
 16 owns with the identical first 24 amino acid sequence found in Synacthen. Compl. ¶
 17 47. Questcor has *never* needed Synacthen to pursue these other indications. It could
 18 have pursued them with Acthar for the last decade. Questcor's purported
 19 "justification" for its conduct is baseless.

20 **F. Retrophin Properly Alleges State Law Claims**

21 As Questcor acknowledges in its moving papers, Retrophin's state law claims
 22 under California's Cartwright Act and Unfair Competition Law rest on the same
 23 allegations as its claims under the federal antitrust laws, and Questcor's motion
 24 therefore fails for the same reasons as described above. Citing *California ex rel. Van*
 25

26 ¹⁶ See *Ritchie*, 342 F.3d at 908-09 (district court could not consider documents
 27 outside the pleadings through incorporation by reference or judicial notice); *Lee*, 250
 28 F.3d at 689-90 (reversing district court's grant of motion to dismiss because the court
 took judicial notice of disputed facts); *United States v. Corinthian Colleges*, 655 F.3d
 984, 999 (9th Cir. 2011) ("[We] may not, on the basis of evidence outside of the
 Complaint, take judicial notice of facts favorable to Defendants that could reasonably
 be disputed.").

1 *de Kamp v. Texaco, Inc.*, Questcor argues that the state law claims also are deficient
 2 because the Cartwright Act does not “apply to a purchase and sale agreement[s], or a
 3 merger between otherwise competing firms.” Mot. at 24 (citing *Texaco*, 46 Cal. 3d at
 4 1168). But as Questcor acknowledges in its motion, *Texaco* was superseded by a
 5 modification to the Cartwright Act that expanded the reach of the act to include such
 6 agreements. *See Stop Youth Addiction, Inc. v. Lucky Stores, Inc.*, 17 Cal. 4th 553, 570
 7 (1998). Accordingly, Questcor makes no showing that Retrophin’s state law claims
 8 should be dismissed.

9 **IV. CONCLUSION**

10 For the foregoing reasons, Retrophin respectfully requests that the Court deny
 11 Questcor’s motion to dismiss. To the extent the Court finds any merit to Questcor’s
 12 motion, Retrophin requests the opportunity to cure any such pleading deficiency by
 13 amendment to the Complaint.

14 Dated: April 4, 2014

KATTEN MUCHIN ROSENMAN LLP

16 By: /s/ Kristin L. Holland
 17 Kristin L. Holland
 18 Attorneys for Plaintiff Retrophin, Inc.